

Appl. No. 10/019,248

REMARKS

Claims 18-23, 25-29, 35-40 and 52-57 have been rejected under 35 USC 102(b) as being anticipated by Torii et al.

This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner will note that Independent claim 52 has been amended to recite the diagnosis of specific disease conditions, and to recite that the diagnosis is performed as a chair-side, bed-side or on-field test in a single step. The importance of the method for diagnosis of the specific recited conditions is discussed in the present application at, for example, the last full paragraph on page 1 through the first full paragraph on page 2, the paragraph bridging pages 16-17 and the paragraph bridging pages 25-26. Applicants submit that the Torii et al. publication, the only cited prior art reference, does not teach or suggest these important aspects of the present invention.

In the Office Action, the Examiner asserts that ARDS, as described in Torii et al., is a "respiratory tract inflammation" as recited in the present claims. However, ARDS is not a lung disease characterized by respiratory tract inflammation, but instead is a lung injury. Torii et al. report results of studies investigating the involvement of the MMPs in the appearance of ARDS in effort to understand the basic mechanism behind the condition. But the reference does not at all teach or suggest that levels of MMPs could be utilized in a method to diagnose respiratory tract diseases, such as those recited in the present claims.

In the Office Action, the Examiner further suggests that the Torii et al. method, specifically the EIA method described by Torii et al., could be utilized within the present invention, particularly in a bed-side, chair-side or an on-field environment. Applicants

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submit, however, that the Torii et al. method cannot at all be utilized in the matter suggested by the Examiner.

The Examiner specifically refers to the concept of one-step sandwich EIA as being commonly used in home pregnancy tests. It appears that the Examiner is either over generalizing these types of tests or is misunderstanding the nature of the two different types of tests. Home pregnancy tests of the type apparently referred to by the Examiner are immunochromatographic tests, namely so-called "dip stick" or immunochromatographic test strip-type tests. This is not the type of method described by Torii et al. For example, the Examiner will note that the section of Torii et al. entitled "Measurements of MMP-2..." discusses the EIA system which involves reactions carried out on a microplate with the plurality of microplate wells. That assay is then analyzed by reading the absorbance by a microplate reader. This is not at all the type of point of care, easy, one-step method according to the present invention.

In view of the above, Applicants submit that Torii et al. did not at all teach the present invention within the meaning of anticipation under 35 USC 102(b), so that the rejection should be withdrawn.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a three (3) month extension of time for filing a response in connection with the present application and the required fee of \$1,020.00 is being submitted concurrently with the Notice of Appeal.

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Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By

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